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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jeffrey A. Hubbell

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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER

JACKSON, MONIQUE R

ART UNIT

PAPER NUMBER

1773

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,787	HUBBELL ET AL.	
	Examiner	Art Unit	
	Monique R. Jackson	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 11, 12, 41, 42 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-9, 11, 12, 41, 42 and 48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/04 & 10/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The preliminary amendment filed 3/19/04 has been entered. Claims 1, 10, 13-40, and 43-47 have been canceled. New claims 48-54 have been added. Claims 2-9, 11, 12, 41, 42 and 48-54 are pending in the application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-6, 8, 9, 11, 12, 41, 48, 49, and 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al (USPN 5,250,613.) Bergstrom et al teach a biopolymer immobilized on a hydrophilic solid surface having a hydrophilic layer comprising a polyethylene imine(PEI)/non-ionic hydrophilic polymer conjugate adsorbed to the solid surface wherein the solid surface has anionic groups capable of reacting with the imino groups of the PEI (*positively charged synthetic polymer*) in the hydrophilic layer (Abstract; Col. 4, lines 62-64.) Bergstrom et al teach that most solid surfaces at normal pH are negatively charged but usually also contain hydrophobic domains and since a protein usually has positive, negative and hydrophobic seats, a protein is attracted to most surfaces by electrostatic attraction as well as hydrophobic interaction (Col. 1, lines 56-64.) Bergstrom et al teach that the coated surface having the immobilized biopolymer has low spontaneous adsorption of proteins and other biopolymers and is an improvement over known hydrophilized surfaces such as those produced by attaching polyethylene glycol (PEG) tails to a solid polymer surface by subjecting the surface to acid

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etching to produce a highly negatively charged polymer surface, then adsorbing a cationic polymer such as PEI to the surface by electrostatic forces, and finally reacting a reactive PEG derivative with available amino groups in the PEI layer; giving a surface having improved repellency of biopolymers (Abstract; Claim 1; Col. 1; Col. 2, lines 28-51.) Bergstrom et al teach the improved coated surface is suitable for use in various biochemical applications including the treatment of implants; and that suitable surfaces are those which have a natural negative net charge, for example silica and glass, or those in which negative charges have been generated by chemical means such as on organic polymer surfaces; wherein the surface may be coated with the conjugate by placing the surface in a solution containing the conjugate (Claim 1; Col. 1; Col. 4, lines 62-68; Col. 5, lines 45-60; Examples.) Bergstrom et al further teach that the soluble conjugate may be a graft polymer (*reads on block copolymer*) of PEI with a hydrophilic non-ionic polymer, suitably nonionic alkylene oxide adducts such as polyethylene glycol (*reads on non-tissue bonding block*), wherein the PEI skeleton has a molecular weight of from 10,000 to 1,000,000, preferably from 50,000 to 500,000; and the hydrophilic polymer or PEG has a molecular weight usually from 500 to 200,000, preferably 1,000 to 100,000; or alternatively, a copolymer of PEI with hydrophilic nonionic polymer by reacting the PEI with ethylene oxide, propylene oxide, butylenes oxide and/or tetrahydrofuran distributed randomly or in blocks or in combination thereof (Col. 3, line 50-Col. 4, line 7; Col. 5, line 34-Col. 7, line 68.) Bergstrom et al teach that the hydrophilic layer formed from the PEI/hydrophilic non-ionic polymer is further reacted with a biopolymer to immobilize the biopolymer to the hydrophilic layer wherein at least 5% of the hydrophilic polymer chains have covalently bonded biopolymers such as proteins, peptides, collagen, carbohydrates, and albumin (Col. 1; Col. 4, lines 8-61; Examples.)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7, 42 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrom et al. The teachings of Bergstrom et al are discussed above. Though Bergstrom et al teach that the solid surface may be any surfaces having a natural negative net charge, such as silica and glass, or a polymer surface that may be chemically modified to produce an anionic surface; Bergstrom et al do not specifically teach that the surface is a metal surface. However, considering Bergstrom et al suggest that the coating may be utilized for treating implants and other surfaces utilized for biochemical applications, one having ordinary skill in the art at the time of the invention would have been motivated to utilize any type of known substrate material utilized in the art wherein the use of metals as well as glass and plastics are known suitable substrate materials for medical devices such as implants. With respect to Claim 7, though Bergstrom et al teach that the hydrophilic layer comprises PEI cationic groups that react with the negatively charged surface to adsorb the hydrophilic layer to the surface, Bergstrom et al do not teach that the hydrophilic polymer or conjugate comprises lysine, histidine, arginine or ornithine monomeric units as cationic blocks. However, Bergstrom et al teach that biopolymers such as proteins, peptides and carbohydrates, may be reacted with or grafted to the hydrophilic conjugate and hence, provides a suggestion to utilize any such biopolymers wherein one skilled

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in the art would have been motivated to include other known cationic polymers or biopolymers in producing the hydrophilic coating layer.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 2-9, 11, 12, 41, 42 and 48-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,743,521, in view of Bergstrom et al or McPherson et al (USPN 6,013,855). Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any suitable substrate material for a medical device or implant wherein metals, ceramics, glass, as well as polymers are known suitable substrate materials as taught by Bergstrom et al (discussed above) or McPherson (Col. 3-Col. 5, line 47.)

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique R. Jackson whose telephone number is 571-272-1508.

The examiner can normally be reached on Mondays-Thursdays, 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Monique R. Jackson
Primary Examiner
Technology Center 1700
June 25, 2006